

REMARKS

A final Office Action mailed August 25, 2004 has been received and carefully reviewed. Claims 1-45 are pending in the application. The Office Action Summary indicates that claims 1-45 are rejected and claims 17-18 have been objected to. As it is unclear if claims 17 and 18 would be allowable if rewritten in independent form, clarification of the allowable status of claims 17 and 18 is requested. Reconsideration and allowance of the claims are respectfully requested in view of the following remarks.

Pursuant to MPEP § 706.07(c)-(d), Applicant formally requests withdrawal of the final rejection of claims 1-45 on the basis that the final rejection of the claims is premature. The final rejection of claims 1-45 is premature because the Examiner has proffered unsound support for finally rejecting claims 1-45, which is inconsistent with the MPEP and case law.

Applicant has endeavored to advance prosecution of the instant application which includes filing responses to first and second non-final office actions (dated 11/15/2002 and 05/14/2003) and a final office action (dated 07/31/2003) in the first prosecution, filing of an RCE and response (dated 12/01/2003), and filing another response to a non-final office action (dated 05/27/2004) in the current (second) prosecution.

In the Examiner's Advisory Action dated 11/18/2003, the Examiner contended that certain differences between Applicant's claimed apparatus and the device of the asserted reference were not given any patentable weight because these differences were functional. In Applicant's response submitted with the RCE dated 12/01/2003, Applicant argued that differences between Applicant's claimed apparatus and the device of the asserted reference must be accorded patentable weight, citing MPEP and Federal Circuit support for Applicant's argument.

In the Examiner's non-final office action dated 03/04/2004, it appears that the Examiner was persuaded that such purported functional limitations should be given patentable weight, and prosecution continued without the Examiner maintaining the previously asserted position on functional limitations. Applicant further advanced

prosecution in its response dated 05/27/2004, in which the claims were subject to further amendment and at which point the application was believed to be in condition for allowance.

The Examiner, in issuing the instant final office action (dated 08/25/2004), appears to have wholly ignored Applicant's substantive arguments on the patentability of claims 1-45 over the asserted art on the sole basis that certain claim limitations that distinguish over the asserted art are "functional."

Applicant is formally requesting withdrawal of the final rejection of claims 1-45 because final rejection of these claims is premature and improper. The Examiner has not given proper consideration to Applicant's claim amendments and supportive arguments, but has instead re-asserted a previously-determined, unsound basis for dismissing Applicant's response dated 05/27/2004. Moreover, the basis for rejecting claims 17 and 18 is improper, as is discussed below. Applicant respectfully requests withdrawal of the final rejection of claims 1-45 pursuant to MPEP § 706.07(c)-(d).

Claims 17 and 18 were objected to under 37 CFR 1.75(c), as being of improper dependent form. The objection of claims 17 and 18 appears to stem from a purported lack of clarity concerning the statutory subject matter of dependent claims 17 and 18 relative to that of claim 1 from which claims 17 and 18 depend.

Applicant refers to MPEP § 608.01(n), sections II, III, which states in part:

The fact that the independent and dependent claims are in different statutory classes does not, in itself, render the latter improper. Thus, if claims 1 recites a specific product, a claim for the method of making the product of claim 1 in a particular manner would be a proper dependent claim Similarly, if claim 1 recites a method of making a product, a claim for a product made by the method of claim 1 could be a proper dependent claim.

Applicant respectfully asserts that claims 17 and 18 comply with 37 CFR 1.75(c), and requests that the Examiner withdraw the objection of claim 17 and 18 under 37 CFR 1.75(c).

Claims 1-5 and 7-45 stand rejected under 35 U.S.C. § 102(b) as being anticipated by *Bednarek et al.* (U.S. Patent No. 6,120,500). Claim 6 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over *Bednarek et al.* (U.S. Patent No. 6,120,500) and further in view of *Sugita et al.* (U.S. Patent No. 4,969,890).

In the Examiner's response to Applicant's arguments presented in the final office action (page 4), the Examiner indicates that Applicant's amendment directed to a "tubular support member rotatable about a longitudinal axis of the stabilizing member when the stabilizing member is deployed outside the tube support member" is a functional limitation to which no patentable weight was given.

In its response dated 05/27/2004 to the non-final office action mailed 03/04/2004, Applicant distinguished Applicant's claimed subject matter from the *Bednarek* apparatus on the basis of structural differences, and not on functional differences as is erroneously contended by the Examiner in the instant final office action.

Each of Applicant's claims 1, 14, 19, and 20 recites the following features, wherein the underlined portion represents the language added by Applicant's responsive amendment dated 05/27/2004:

Claim 1:

c. a stabilizing member deployable outside the tubular support member and configured to maintain alignment of the tubular support member within the right atrium, the tubular support member rotatable about a longitudinal axis of the stabilizing member when the stabilizing member is deployed outside the tubular support member.

Claim 14:

c. a second opening in the distal shaft section providing external access to, and in fluid communication with, the second lumen in the elongated shaft and configured to facilitate advancement of a support stabilizing member through the second opening and into the right atrium, a longitudinal axis of the second lumen aligned relative to the second opening to facilitate rotation of the tubular support member about a longitudinal axis of the stabilizing member when the stabilizing member is deployed beyond the second opening.

Claim 19:

c. a stabilizing means deployable outside the tubular support means and configured to maintain the alignment of the tubular support means within the right

atrium, the tubular support means rotatable about a longitudinal axis of the stabilizing means when the stabilizing means is deployed outside the tubular support means.

Claim 20:

means, deployable outside the tubular support member via the second opening, for stabilizing the tubular support member within the right atrium, the tubular support member rotatable about a longitudinal axis of the stabilizing means when the stabilizing means is deployed outside the tubular support member.

Applicant respectfully asserts that recitation of the tubular support member and its physical association with stabilizing member/means in the recited deployed configuration is a structural feature, and not a functional feature as is apparently contended by the Examiner.

Defining structures in terms of interrelationships or attributes they must possess has been long sanctioned in the case law. In In re Venezia, 530 F.2d 956, 189 U.S.P.Q. 149 (CCPA 1976), for example, the court made clear that language such as “each sleeve of said pair adapted to be fitted over the insulating jacket of one or said cables . . . imparts a structural limitation to the sleeve.” *Id.* at 959 (*emphasis in original*). The court went on to clarify that language such as “adapted to be affixed” and “adapted to be positioned” defines structures or attributes of the element in question and limits the element to those configurations which allow for the stated interrelation of the element with other structures. *Id.*

Moreover, assuming *arguendo*, if Applicant’s recitation of the deployed stabilizing member/means in the rejected claims was construed to include functional aspects, Applicant respectfully asserts that the Examiner’s disregarding of such functional aspects is improper. For example, MPEP § 2173.05(g) makes clear that:

A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what is fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. *Emphasis added.*

Moreover, In Ex parte Bylund, 217, U.S.P.Q. 492 (Bd. Pat. App. 1981), for example, the Board made the following statement on the issue of functional language in claims:

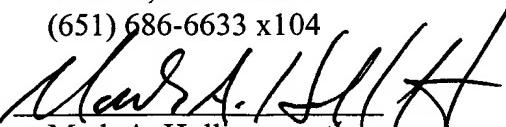
Although we have sustained several of the Examiner's rejections, we here wish to specifically note that contrary to the Examiner's assertions, functional language in the claims must be given full weight and may not be disregarded in evaluating the patentability of the subject matter defined employing such functional language. *Id* at 498 (*emphasis added*).

Applicant respectfully asserts that the Examiner is compelled by the MPEP and by the case law to give full weight to the language of Applicant's rejected claims, and not to disregard this language in evaluating the patentability of claims 1-45. Because the Examiner has not properly followed examination procedure in this regard, final rejection of the pending claims is premature, and must be withdrawn.

Assuming the Examiner properly withdraws finality of the present rejections, Applicant reiterates in full the arguments for patentability presented in its responsive amendment dated 05/27/2004.

It is believed that, in view of the arguments above and in the responsive amendment dated 05/27/2004, claims 1-45 are in condition for allowance. The Examiner is invited to contact Applicant's Representatives, at the below-listed telephone number, if there are any questions regarding this Response, or if prosecution of this application may be assisted thereby.

Respectfully submitted,
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